DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 9, 2014

C.R. Bard, Inc.
% Laurie Sang
Regulatory Affairs Specialist
1625 W. Third St.
Tempe, Arizona 85281

Re: K143208
Trade/Device Name: Denali Filter System – Femoral, Jugular/Subclavian Delivery Kit
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular Intravascular Filter
Regulatory Class: Class II
Product Code: DTK
Dated: November 7, 2014
Received: November 10, 2014

Dear Laurie Sang,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143208

Device Name
Denali® Filter System – Femoral and Jugular/Subclavian Delivery Kit

Indications for Use *(Describe)*

The Denali® Filter is indicated for use in the prevention of recurrent pulmonary embolism via placement in the vena cava in the following situations:

-Pulmonary thromboembolism when anticoagulants are contraindicated.
-Failure of anticoagulant therapy for thromboembolic disease.
-Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
-Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The Denali® Filter may be removed according to the instructions supplied under the Section labeled: Optional Procedure for Filter Removal.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DENALI® Filter System
510(k) Summary
21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

Submitter Information:

Applicant:	Bard Peripheral Vascular, Inc 1625 West 3rd Street Tempe, Arizona 85281
Phone:	480-350-6069
Fax:	480-449-2546
Contact:	Laurie Sang, Regulatory Affairs Specialist
Date:	November 7, 2014

Subject Device Name:

Device Trade Name:	**Denali® Filter System – Femoral and Jugular/Subclavian Delivery Kit**
Common or Usual Name:	Filter, Intravascular, Cardiovascular
Classification:	Class II
Classification Panel:	Cardiovascular Devices
Product Code:	DTK
Predicate Devices:	(K130366; Clearance May 15, 2013)

Summary of Change:

The modification from the predicate device, compared to the subject Denali® Filter System - Femoral and Jugular/Subclavian Delivery Kit, is the device will include two introducers, a 10 French dilator and an 8 French dilator and pusher system. The new design will also incorporate a longer handle on the delivery system. Minor changes have been made to the device labeling.

Device Description:

The Denali® Vena Cava Filter is a venous interruption device designed to prevent pulmonary embolism. The Denali® Filter can be delivered via the femoral and jugular/subclavian approaches. A separate delivery system is available for each approach. The Denali® Filter is designed to act as a permanent filter. When clinically indicated, the Denali® Filter may be percutaneously removed after implantation according to the instructions provided under the "Optional Procedure for Filter Removal" section.

The Denali® Filter of twelve shape-memory laser-cut nickel-titanium appendages. These twelve appendages form two levels of filtration with the legs providing the lower level of filtration and the arms providing the upper level of filtration. The Denali® Filter is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28mm.

The Denali® Vena Cava Filter System consists of a short, 15cm, 10 French dilator, an introducer sheath, a long, 55cm, 8 French dilator, and a preloaded Denali® Filter in a storage tube with a pusher. The 15cm, 10 French dilator accepts a 0.035" guidewire and is intended for pre-dilatation. The long, 55cm, 8 French dilator accepts a 0.035" guidewire and allows for an 800 psi maximum pressure contrast power injection. Radiopaque marker bands on the end of the dilator aid in measuring the maximum indicated IVC diameter. They are spaced at a distance of 28mm (outer-to-outer). The 55cm, 8.4 French I.D. introducer sheath contains a radiopaque marker and hemostasis valve with a side port. The pusher advances the filter through the introducer sheath to the predeployment mark and is then used to fix the filter in place while the filter is unsheathed.

Indications for Use of Device:

The Denali® Filter is indicated for use in the prevention of recurrent pulmonary embolism via placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated
- Failure of anticoagulant therapy for thromboembolic disease
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced

- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The Denali® Filter may be removed according to the instructions supplied under the Section labeled: Optional Procedure for Filter Removal.

Technological Comparison to Predicate Devices:

The technological characteristics of the subject device, the Denali® Filter System - Femoral and Jugular/Subclavian Delivery Kit, are substantially equivalent to those of the predicate devices, in terms of the following:

- Intended use
- Indications for use
- Target population
- Delivery system design
- Filter design and material
- Fundamental scientific technology
- Packaging configuration (with addition of the extra dilator)
- Sterility Assurance and method of Sterilization

Performance Testing Summary:

To demonstrate substantial equivalence of the subject device to the predicate device, the technological characteristics and performance criteria were evaluated using *in vitro* testing performed as outlined below:

In Vitro Delivery System Testing

- Dimensional and Visual Inspection
- Delivery System Component Tensile Testing
- Simulated Use Testing
- Packaging Testing

The results from these tests demonstrate that the technological characteristics and performance of the Denali® Filter System - Femoral and Jugular/Subclavian Delivery Kit is comparable to the predicate device and that the subject device can perform in a manner substantially equivalent to the predicate device with the same intended use.

Conclusion:

The subject Denali Filter System met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The Denali® Filter System - Femoral and Jugular/Subclavian Delivery Kit is substantially equivalent to the legally marketed predicate device.